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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,472	12/12/2003	Marc F. Charette	JJJ-P02-510	9598

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FISH & NEAVE IP GROUP
ROPES & GRAY LLP
ONE INTERNATIONAL PLACE
BOSTON, MA 02110-2624

EXAMINER	
WANG, CHANG YU	
ART UNIT	**PAPER NUMBER**
1649	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/734,472	**Applicant(s)** CHARETTE, MARC F.	
	Examiner Chang-Yu Wang	**Art Unit** 1649	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 March 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): 112-1st new matter.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *27-32,34-38,43,44,46,48 and 51-53*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER

Continuation of 11. does NOT place the application in condition for allowance because:
The amended claims 27, 46, 48 and new claim 53 require additional search to analyze whether the claims are anticipated or obvious over the prior art. The amended claims are not entered because the newly added limitation of hippocampal damage caused by permanent or transient global ischemia in claim 27 and the deletion of the limitation of ethanol, senility in claim 48 require additional search and analyses to determine whether they are anticipate/obvious over the prior art.

The lined-through references listed in the IDS filed February 12, 2004 have not been considered because they cannot be found in the parent application 09/012846.
The requirement of a new oath/declaration is withdrawn in response to Applicant's amendment.
The objection to the specification as introducing new matter into the disclosure is withdrawn in response to Applicant's amendment.
The rejection of claim 34 under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement due to new matter is withdrawn in response to Applicant's amendment to the claim.
The rejection of claims 27-38, 43-44, 46, 48 under 35 U.S.C. 112, first paragraph because the specification does not enable the invention commensurate in scope with the claims is maintained for reasons of record in the previous office action. The rejection is also applied to new claims 51-53. Applicant argues that the amended claims are enabled because the in vitro data in the instant disclosure can predict the effects on reducing memory dysfunction associated with damaged hippocampal tissue in a mammal in vivo. Applicant's arguments have been fully considered but they are not persuasive. Based on the disclosure and prior art, Applicant is enabled for a method of enhancing synaptogenesis for neuronal survival in the hippocampus in vivo by administration of OP-1 to a subject. However, Applicant is not enabled for a method of reducing memory dysfunction associated with damaged hippocampal tissue since memory function is complex and is involved in more than neural survival and dendritic development. To restore memory function requires reconnecting the damaged neurons and reestablishing synaptic plasticity that are involved in memory dysfunction and cognitive function of the brain. Since the neuronal connection and synaptic plasticity that are involved in memory dysfunction are unclear, it is unpredictable whether administration of OP-1 would repair all the molecular elements that are damaged in memory dysfunction. Applicant fails to demonstrate that administration of OP-1 or related fragments as recited in the claims to a patient or animal suffering from memory dysfunction associated with damaged hippocampal tissue would reconnect all the damaged neurons and reestablish all the synaptic plasticity that are involved in memory dysfunction and cognitive function of the brain. It is also unpredictable whether intraventricular administration of OP-1 at any concentration in the brain would achieve a balance of different morphogens that can enhance synapse formation and establishing synaptic plasticity that are required for reducing memory dysfunction since axonal guidance and synapse formation require a balance of concentration of different morphogens.
The rejection of claims 27-32, 34-38, 43-44, 46, 48 under 35 U.S.C. 102 (e) as being anticipated by U. S. Patent No. 6723698 (Rueger et al. issued on April 20, 2004, effective filling date September 25, 1997) is maintained for reasons of record in the previous office action. The rejection is also applied to new claims 51-53 because new claims recite limitations of malnutrition, metabolic disorder and anorexia are within the scope of the original claims.
Applicant argues that US6723698 does not teach new limitation of hippocampal damage caused by permanent or transient global ischemia. '698 does not teach biocompatible microspheres, other neurotoxin, maltnutrition or metabolic disorders. '698 teaches intraventricular administration as in claim 43 (see col. 20, lines 20-25) and biocompatible microspheres as in claim 44 (see col. 21, lines 5-25). '698 also teaches administration of OP-1 to prevent neuronal cell death caused by ischemia as in claims 40-41 (col.36 example 11), traumatic brain injury as in claim 42 (col. 53, example 20), mechanical/chemical trauma/ neurotoxin including ethanol as in claims 39, 45-46 (see col. 30, example 6), malnutrition, metabolic disorders as in claims 48, 51 and 52 (col.1, lines 42-50) and anorexia in claim 53 would consequently result in malnutrition and metabolic disorder as in claims 48, 51 and 52.
The rejection of claims 27-32, 34-38, 43-44, 46, 48 under 35 U.S.C. 103(a) as being unpatentable over US 6723698 (Rueger et al. issued on April 20, 2004, effective filling date September 25, 1997) in view of Kern et al. (Neurotoxicity. 1993. 14: 319-27) is maintained for reasons of record in the previous office action and the reasons as set forth above. The rejection is also applied to new claims 51-53 because new claims recite limitations of malnutrition, metabolic disorder and anorexia are within the scope of the original claims.